

### REMARKS

Claims 1-59 are pending. Claims 2, 4-6, 13, 15-23, 26-52, 54, and 55 are drawn to nonelected subject matter and are cancelled without prejudice. Applicants point out that claim 59 was added as a new claim in Applicants' reply filed on August 11, 2003. Claim 59 depends from claim 1, which is presently under consideration. The only difference between claim 1 and claim 59 concerns the scope of  $R^{12}$ . Specifically, the definition of  $R^{12}$  in claim 59 excludes hydrogen. Applicants submit that claim 59 reads on the elected species and is drawn to elected subject matter, and Applicants respectfully request that claim 59 be examined in concert with remaining pending claims 1, 3, 7-12, 14, 24, 25, 53, and 56-58.

Claims 1, 24, and 53 have been rejected under 35 U.S.C. 102(b) as being anticipated by Hale et al., U.S. Patent 5,622,944 (Hale). According to the Action:

Hale et al. teach prodrugs of 17-hydroxy sterol compounds such as androsta-3,5-diene-3,17-diol, bis[4-(trimethylammonio)butanoate], dibromide and compositions comprising said prodrugs (see the entire article, especially Figure 1d). The compound and composition taught by the reference are encompassed by the instant claims (Action, page 3, part 6).

Applicants respectfully disagree.

#### *The Hale Steroid*

The compound disclosed in Figure 1d of Hale has structural formula (A) (see "Attachment"). The Hale steroid corresponds to a compound having formula (I) in claims 1, 24, and 53 in which substituents  $R^1$ - $R^{14}$  and  $R^{17}$  have the values given in Table 1 (also shown in the "Attachment").

The substituents  $R^1$ - $R^{14}$  in formula (I) represent those substituents that are attached to the A, B, and C rings of the steroid nucleus. With the sole exception of  $R^3$ , all of the A/B/C ring

substituents in the Hale steroid (i.e.,  $R^1$ ,  $R^2$ , and  $R^4$ - $R^{14}$ ) are either hydrogen or  $CH_3$ , or are deleted to form a double bond.

$R^{17}$  in formula (I) is a substituent associated with the D ring of the steroid nucleus. The substituent corresponding to  $R^{17}$  in the Hale steroid is  $-OC(O)CH_2CH_2CH_2N^+(CH_3)_3$ .

### *The Claimed Compounds and Pharmaceutical Compositions*

Claims 1 and 53 are directed to steroid compounds having formula (I). Claim 24 is directed to a pharmaceutical composition comprising an effective amount of a compound having formula (I).

Claims 1, 24, and 53 all require "that at least two of  $R^1$  through  $R^{14}$  are independently selected from the group consisting of a substituted or unsubstituted (C1-C10) aminoalkoxy, (C1-C10) alkylcarboxy-(C1-C10) alkyl, (C1-C10) alkylamino- (C1-C10) alkylamino, (C1-C10) alkylamino- (C1-C10) alkylamino- (C1-C10) alkylamino, a substituted or unsubstituted (C1-C10) aminoalkylcarboxy, a substituted or unsubstituted arylamino- (C1-C10) alkyl, a substituted or unsubstituted (C1-C10) aminoalkoxy -(C1-C10) alkyl, a substituted or unsubstituted (C1-C10) aminoalkylaminocarbonyl, (C1-C10) quaternaryammonium alkylcarboxy,  $H_2N-HC(Q_5)-C(O)-O-$ ,  $H_2N-HC(Q_5)-C(O)-N(H)-$ , (C1-C10) azidoalkoxy, (C1-C10) cyanoalkoxy, P.G.- $HN-HC(Q_5)-C(O)-O-$ , (C1-C10) guanidinoalkoxy, and (C1-C10) guanidinoalkylcarboxy..." (the entirety of the substituent group (C1-C10) aminoalkoxy...(C1-C10) guanidinoalkylcarboxy is referred to collectively as the "proviso substituent group"). This limitation on the identity on  $R^1$  through  $R^{14}$  is expressly stated in the proviso set forth at the end of claims 1, 24, and 53. In other words, at least two of the A/B/C ring substituents in the claimed compounds (i.e.,  $R^1$ - $R^{14}$ ) must be substituents belonging to the proviso substituent group recited above. Applicants point out that the proviso substituent group excludes both hydrogen and  $CH_3$ .

The difference between claim 1 and claim 53 concerns the scope of  $R^{17}$ . In claim 1,  $R^{17}$  can be selected from the same pool of substituents that is available to  $R^1$ - $R^4$ ,  $R^6$ ,  $R^7$ ,  $R^{11}$ ,  $R^{12}$ ,  $R^{15}$ , and  $R^{16}$ . In claim 53,  $R^{17}$  can only be alkylcarboxyalkyl or poly(aminoalkyl).

As pointed out above, all but one of the substituents corresponding to  $R^1$ - $R^{14}$  in the Hale steroid is either hydrogen,  $CH_3$ , or deleted to form a double bond. In other words, 13 of the 14 A/B/C ring substituents in the Hale steroid do not meet the structural criteria of the proviso substituent group. Stated another way, the Hale steroid does not have at least two substituents from the proviso substituent group attached to rings A/B/C of the steroid nucleus. Claims 1, 24, and 53, on the other hand, require that two substituents from the proviso substituent group be attached to rings A/B/C of the steroid nucleus. Therefore, the Hale steroid falls outside of the scope of claims 1, 24, and 53.

A further difference between the Hale steroid and claim 53 concerns the identity of  $R^{17}$ . Claim 53 requires that  $R^{17}$  be an alkylcarboxyalkyl or a poly(aminoalkyl) group. The substituent corresponding to  $R^{17}$  in the Hale steroid is  $-OC(O)CH_2CH_2CH_2N^+(CH_3)_3$  and is an example of a quaternary ammonium alkylcarboxy group, which is different from both the alkylcarboxyalkyl or a poly(aminoalkyl) group (the two possible substituents for  $R^{17}$  in claim 53).

Applicants submit that the Hale steroid does not read on claims 1, 24, and 53. Therefore, Hale does not anticipate these claims. Applicants therefore respectfully request withdrawal of the rejection.

Since claims 1, 24, and 53 are not anticipated by Hale, then claims 3, 7-12, and 14 (which depend from claim 1); claim 25 (which depends from claim 24); and claims 56-58 (which depend from claim 53) do not depend from a rejected base claim. Applicants respectfully request that the objection to these claims be withdrawn.

No fee is believed due with this response. Please apply any charges or credits to deposit account 06-1050, referencing Attorney Docket No.: 07913-006001.

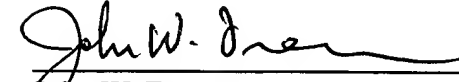
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Respectfully submitted,

Date: \_\_\_\_\_

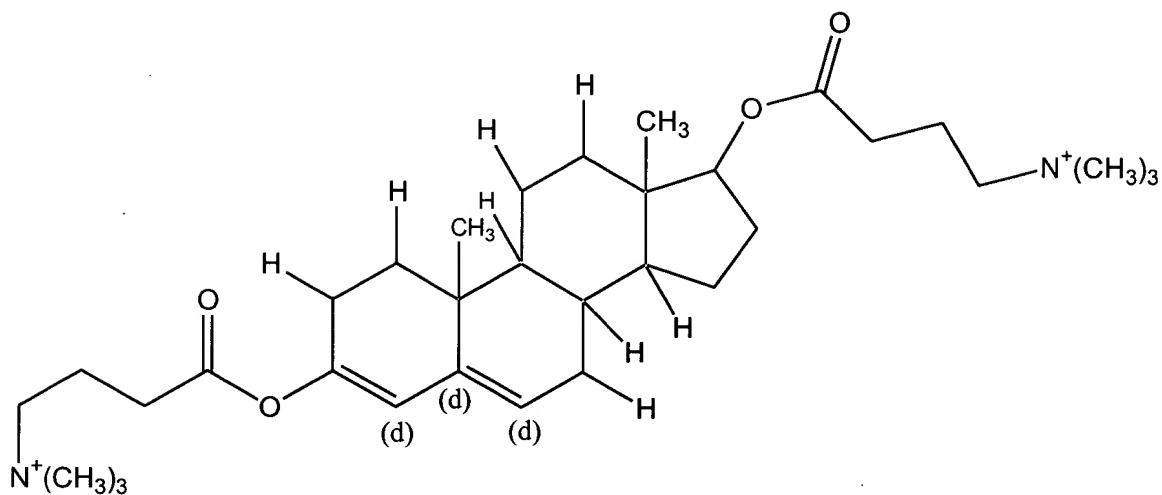
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# ATTACHMENT



**Table 1**

$R^1$	H
$R^2$	H
$R^3$	$-OC(O)CH_2CH_2CH_2N^+(CH_3)_3$
$R^4$	(d) Deleted to form double bond
$R^5$	(d) Deleted to form double bond
$R^6$	(d) Deleted to form double bond
$R^7$	H
$R^8$	H
$R^9$	$CH_3$
$R^{10}$	H
$R^{11}$	H
$R^{12}$	H
$R^{13}$	$CH_3$
$R^{14}$	H
$R^{17}$	$-OC(O)CH_2CH_2CH_2N^+(CH_3)_3$